

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NORTH CAROLINA  
WESTERN DIVISION**  
Civil Action No. 5:07-cv-00389-F

CORNERSTONE BIOPHARMA, INC. and )	)	<b>DEFENDANTS' MEMORANDUM IN SUPPORT OF MOTION TO STAY ACTION PENDING REEXAMINATION OF U.S. PATENT NO. 6,270,796</b>
J-MED PHARMACEUTICALS, INC., )		
)	)	
Plaintiffs, )		
)	)	
v. )		
)	)	
VISION PHARMA, LLC, )		
SANDER BUSMAN, THOMAS )	)	
DESTEFANO, MICHAEL MCALOOSE )		
and NEXGEN PHARMA, INC., )	)	
Defendants. )		
)		

## I. INTRODUCTION

Defendants Vision Pharma, LLC (“Vision”), Nexgen Pharma, Inc. (“Nexgen”), Sander Busman (“Busman”), Thomas DeStefano (“DeStefano”) and Michael McAloose (“McAloose”) (collectively, “Defendants”) hereby submit this memorandum in support of their motion for a stay of the above-captioned action.<sup>1</sup> Defendants request that this action be stayed in its entirety (including answering the Amended Complaint) pending the outcome of the United States Patent and Trademark Office’s (“USPTO”) reexamination of the patent asserted in this action by Plaintiffs Cornerstone BioPharma, Inc. (“Cornerstone”) and J-Med Pharmaceuticals, Inc. (“J-Med”) (collectively, “Plaintiffs”).

Notwithstanding that the patent-in-suit is in reexamination with the USPTO and that all claims have been rejected as unpatentable, Plaintiffs commenced an action for patent infringement against Defendants. As set forth more fully below, when the patent-in-suit is the

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<sup>1</sup> By filing this motion and memorandum in support thereof, Defendants do not waive, and expressly reserve, any and all defenses available to them.

subject of a reexamination proceeding in the USPTO, courts routinely stay such patent infringement cases pending the outcome of the reexamination proceeding. The purpose of the stay is to prevent the waste of both the court's and the parties' time and resources. Reexamination provides a determination of patent invalidity, in an impartial forum (the USPTO), at almost 100 times less cost to the parties than litigation, and by those who are specially trained to understand the technologies described in patents (*i.e.*, examiners). *See Canady v. Erbe Electromedizin, GMBH*, 271 F. Supp. 2d 64, 68 (D.D.C. 2002). Indeed, Congress intended that the USPTO's reexamination proceedings "could settle validity disputes more quickly and less expensively than the often protracted litigation involved in such cases" and "would allow courts to refer patent validity questions to the expertise of the Patent Office." *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 602 (Fed. Cir. 1985).

The outcome of the pending reexamination before the USPTO of the patent-in-suit could dramatically impact the issues in this case, including the validity of the patent-in-suit and various infringement issues. Moreover, this action is in its infancy – only a Complaint and Amended Complaint have been filed, and none of the Defendants have filed an answer or otherwise responded to the Amended Complaint (because their time for response has not yet expired). A stay in this case will not cause any undue prejudice to the Plaintiffs, and indeed, a stay will benefit all parties as well as this Court.

## **II. BACKGROUND**

### **A. The Reexamination of the Patent-in-Suit**

On July 7, 2006, a request for *ex parte* reexamination of all eighteen (18) claims of the U.S. Patent No. 6,270,796 ("the '796 patent") was filed in the USPTO by a third party. The USPTO granted the reexamination request on September 14, 2006, finding that the request raised

a substantial new question of patentability. The reexamination of the ‘796 patent currently is pending before the USPTO.

On March 7, 2007, the USPTO issued the first Office Action on the Merits, rejecting all 18 claims of the ‘796 patent. In the first Office Action, the Examiner found, among other things, that all 18 claims of the ‘796 patent were unpatentable in view of various prior art patents and printed publications.<sup>2</sup> A response to the first Office Action was filed on May 4, 2007. As of the filing date of this motion and memorandum, all 18 claims of the ‘796 patent remain rejected as anticipated and/or obvious in view of various prior art patents and printed publications. The outcome of the reexamination can range from canceling any and all claims that are unpatentable, amending some or all claims, or confirming the patentability of some or all claims. *See 35 U.S.C. § 307(a).*

## **B. The Alleged Infringement**

J-Med claims to be the assignee of the ‘796 patent, and Cornerstone claims to be the exclusive licensee of the ‘796 patent, which generally relates to a prepackaged therapeutic regimen for the temporary relief of symptoms associated with rhinitis through the use of antihistamines and/or decongestants. Amended Complaint at ¶¶ 2, 16-17. Cornerstone marks its AlleRx Dose Pack as being covered by the ‘796 patent.

Vision is a New Jersey limited liability company with its principal place of business in Wall, New Jersey and Nexgen is a California corporation with its principal place of business in Irvine, California. Messrs. Busman, DeStefano and McAloose are individuals that are members

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<sup>2</sup> In rejecting the claims of the ‘796 patent, the USPTO has cited the following prior art: U.S. Patent No. 6,564,945; U.S. Patent No 5,830,490; U.S. Patent No. 6,077,530; U.S. Patent No. 4,295,567; Meltzer, E.O. “Antihistamine and Decongestant-Induced Performance Decrements” J. OCCUP. MED. 1990, 32(4), 327-34; GOODMAN AND GILMAN’S THE PHARMACOLOGICAL BASIS OF THERAPEUTICS, 6<sup>th</sup> Ed., MacMillan Publishing Co., Inc. New York, pp. 623 (1980); and Howrie, Denise L, et al., *Phenylpropanolamine-Induced Hypertensive Seizures*, J. PEDIATRICS, pp. 143-144 (January 1983).

of Vision.<sup>3</sup> Vision produces a product marketed as VisRx, which is the accused product that is the subject of this action.

Even though the ‘796 patent currently is before the USPTO in a pending reexamination proceeding (and all 18 claims of the ‘796 patent have been rejected as unpatentable), Plaintiffs sued Vision and Nexgen in this Court on October 8, 2007, alleging that the VisRx product infringes the ‘796 patent, that the VisRx product infringes Plaintiffs’ copyright rights, and that the Defendants have engaged in unfair competition. On November 19, 2007, Plaintiffs filed an Amended Complaint, which named Messrs. Busman, DeStefano and McAloose as defendants and asserted individual claims against the individual defendants based on the alleged conduct by Vision.

### **III. ARGUMENT**

A district court has the inherent power to control its docket in order to conserve judicial resources and provide for the just determination of pending cases. *Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1426-27 (Fed. Cir. 1988); *L.E.A. Dynatech, Inc. v. F. Allina*, 40 F.3d 1527, 1530 (Fed. Cir. 1995). This power includes the authority to order, in the interest of justice, a stay pending the outcome of a patent validity challenge. *Id.*; *Gould v. Control Laser Corp.*, 705 F.2d 1340, 1341 (Fed. Cir. 1983). In this regard, stays of patent infringement cases are routinely granted pending the outcome of reexamination proceedings to prevent the waste of both the court’s and the parties’ time and resources. *ASCII Corp. v. STD Entertainment USA, Inc.*, 844 F. Supp. 1378, 1381 (N.D. Cal. 1994) (stay granted even before request for reexamination was

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<sup>3</sup> In its Amended Complaint, Plaintiffs have asserted individual claims against Messrs. Busman, DeStefano and McAloose. There is no basis for Plaintiffs’ claims against the individual defendants based on alleged conduct by Vision. Defendants expect that the claims against Messrs. Busman, DeStefano, and McAloose will be dismissed if and when the ‘796 patent comes out of reexamination.

filed); *GPAC, Inc. v. D.W.W. Enterprs. Inc.*, 144 F.R.D. 60, 62 (D.N.J. 1992) (stating that Congress noted its approval of district courts liberally granting stays pending reexamination).

Reexamination provides a determination of patent invalidity, in an impartial forum (the USPTO), at almost 100 times less cost to the parties than litigation, and by those who are specially trained to understand the technologies described in patents (*i.e.*, examiners). *See Canady v. Erbe Electromedizin, GMBH*, 271 F. Supp. 2d 64, 68 (D.D.C. 2002). Indeed, Congress intended that the USPTO's reexamination proceedings "could settle validity disputes more quickly and less expensively than the often protracted litigation involved in such cases" and "would allow courts to refer patent validity questions to the expertise of the Patent Office." *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 602 (Fed. Cir. 1985); *see also Ingro v. Tyco Industries, Inc.*, 227 U.S.P.Q. 69, 80 (N.D. Ill. 1985) ("Congress enacted the reexamination procedure to provide an inexpensive, expedient means of determining patent validity which, if available and practical, should be deferred to by the courts....") (emphasis added). As courts have recognized, reexamination provides additional substantial benefits:

- (1) All prior art presented to the Court will have been first considered by the USPTO, with its particular expertise;
- (2) Many discovery problems relating to the prior art can be alleviated by the USPTO reexamination;
- (3) In those cases resulting in effective invalidity of the patent, the suit will likely be dismissed;
- (4) The outcome of the reexamination may encourage a settlement without the further use of the Court;
- (5) The record of reexamination would likely be entered at trial, thereby reducing the complexity and length of the litigation;
- (6) Issues, defenses and evidence will be more easily limited in pre-trial conference after a reexamination; and

(7) The cost will likely be reduced both for the parties and the Court.

*See Softview Computer Prods. Corp. v. Haworth, Inc.*, 56 U.S.P.Q.2d 1633, \*2 (S.D.N.Y. 2000) (citing *Emhart Indus. Inc. v. Sankyo Seiki Mfg. Ltd.*, 3 U.S.P.Q.2d 1889, 1890 (N.D. Ill. 1987)).

In deciding whether to stay patent litigation, district courts generally consider (1) whether a stay would unduly prejudice the non-moving party or present a clear tactical advantage for the moving party; (2) whether a stay will simplify the issues; and (3) whether discovery is complete and a trial date has been set. *In re Laughlin Prods., Inc.*, 265 F. Supp. 2d 525, 530-31 (E.D. Pa. 2003); *Xerox Corp. v. 3Com Corp.*, 69 F. Supp. 2d 404, 406 (W.D.N.Y. 1999). These factors weigh strongly in favor of granting a stay of this litigation.

**1. A Stay Will Not Cause Undue Prejudice to the Plaintiffs Nor Will It Present a Clear Tactical Advantage for the Defendants.**

Staying this action pending the outcome of the reexamination of the '796 patent will not result in any undue prejudice to the Plaintiffs nor will it present a clear tactical advantage for the Defendants. It is the district court's responsibility to weigh the competing interests of the parties when deciding whether to grant a motion to stay. *Landis v. North America*, 299 U.S. 248, 255 (1936).

Given that this case is in the earliest stages of litigation, a stay pending reexamination is entirely appropriate. To date, answers have not been filed, a scheduling order has not been set, discovery has not begun nor has a trial date been set. The instant action has not proceeded to a point where granting a stay would result in any prejudice to Plaintiffs whatsoever. Further, the delay inherent in the reexamination proceedings does not constitute, by itself, undue prejudice. *Pegasus Dev. Corp. v. DirecTV, Inc.*, 2003 WL 211057073, at \*2 (D. Del. May 14, 2003). In fact, the USPTO accelerates reexamination when the patent is involved in stayed litigation. See Manual of Patent Examining Procedure ("MPEP") §§ 2261, 2263. Further, any cost incurred

due to delay is offset by the gains to be achieved by obtaining the USPTO's guidance in this matter.

Moreover, the Defendants will be prejudiced should the motion to stay be denied, as the Defendants will be forced to devote significant time, cost and resources into litigating the case even though there is a very real probability that the patent-in-suit will be impacted by the reexamination. However, such costs and burdens will be unnecessary if the reexamination by the USPTO cancels or amends some or all of the claims of the patent-in-suit. Additionally, even if the claims are not cancelled, all parties will benefit from streamlining of the case that will undoubtedly occur.

Furthermore, while a stay would provide several benefits to both parties and the Court, none of these benefits would result in a clear tactical advantage for Defendants. The validity of the '796 patent pending before the USPTO is the identical issue that the Defendants will raise as a defense to the alleged infringement.<sup>4</sup> There is no tactical advantage to Defendants or a tactical disadvantage to the Plaintiffs in having this issue addressed before the USPTO rather than initially by this Court. Indeed, the Court and the parties will benefit from the USPTO's expert consideration of the new prior art. *Gould*, 705 F.23d 1342.

Accordingly, because a stay will result in no prejudice to Plaintiffs and no tactical advantage for Defendants, a stay of this action is proper.

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<sup>4</sup> The USPTO is considering and has relied on various prior art references in rejecting the claims of the '796 patent, including U.S. Patent No. 6,564,945; U.S. Patent No 5,830,490; U.S. Patent No. 6,077,530; U.S. Patent No. 4,295,567; Meltzer, E.O. "Antihistamine and Decongestant-Induced Performance Decrements" J. OCCUP. MED. 1990, 32(4), 327-34; GOODMAN AND GILMAN'S THE PHARMACOLOGICAL BASIS OF THERAPEUTICS, 6<sup>th</sup> Ed., MacMillan Publishing Co., Inc. New York, pp. 623 (1980); and Howrie, Denise L, et al., *Phenylpropanolamine-Induced Hypertensive Seizures*, J. PEDIATRICS, pp. 143-144 (January 1983). The Court should allow the USPTO to consider these and other prior art references to avoid duplicative work or inconsistent results.

## **2. A Stay Pending the Outcome of the Reexamination Will Simplify the Issues.**

If litigation is not stayed during a reexamination, the risk is that the Court and the parties will spend significant effort litigating the validity of claims that are ultimately either rejected altogether or modified. As one court noted:

The final form of the claims therefore will remain uncertain until the conclusion of the reexamination procedure. It makes sense to ascertain the ultimate scope of the claims before trying to figure out whether defendants' products infringe the patent-in-suit. Absent a stay, the parties may end up conducting a significantly wider scope of discovery than necessary, and the court may waste time examining the validity of claims which are modified or eliminated altogether during reexamination.

*Target Therapeutics, Inc. v. SciMed Life Sys., Inc.*, No. C-94-20775, 1995 WL 20470, at \*2 (N.D. Cal. Jan. 13, 1995) (emphasis added). In fact, a stay is appropriate where “the outcome of the reexamination would be likely to assist the court in determining patent validity and, if the claims were canceled in the reexamination, would eliminate the need to try the infringement issue.”” *Lincoln Elec. Co. v. Miller Elec. Mfg. Co. et al.*, No 1:06 CV 02981, 2007 WL 2670039, at 1 (N.D. Ohio Sept. 7, 2007) (quoting *Slip Track Sys., Inc. v. Brady*, 159 F.3d 1337, 1341 (Fed. Cir. 1998)).

Many courts have recognized the benefits of awaiting resolution of a reexamination by the USPTO. For example, in *Loffland Brothers Co. v. Mid-Western Energy Corp.*, 225 U.S.P.Q. 886 (W.D. Okla. 1985), the court granted a stay because it found that the determination by the USPTO would simplify the issues for trial stating:

Indeed, the Court invites the final determination by the [US]PTO as to the validity of plaintiff's patent claims. The reexamination procedure has the potential to eliminate trial on the issue of patent infringement, should all of the patent's claims be cancelled. It is equally possible for all the claims in plaintiff's patent to be upheld, or to be narrowed in some degree. In any event, the expert view of the Patent Office examiner will certainly benefit this Court.

*Id.* at 887; *see also Ethicon*, 849 F.2d at 1429 (noting that “even if the reexamination did not lead to claim amendment or cancellation, it could still provide valuable analysis to the district court, which it could consider in reaching its determination”).

In this case, as in the above-cited cases, a stay will likely serve to simplify the issues in question and simplify a trial of the case.<sup>5</sup> Thus, it is only efficient and prudent to await the result of the reexamination by the USPTO before proceeding with this case. To litigate cases while the validity and scope of the claims are currently being examined by the USPTO would only be a waste of the parties’ and the Court’s resources were the USPTO to cancel and/or amend some or all of the claims.

This is especially true in light of the recent adoption of the Local Patent Rules in the Eastern District of North Carolina, which took effect on September 17, 2007. The Local Patent Rules require the party asserting patent infringement to disclose asserted claims and provide preliminary infringement contentions within thirty (30) days of the initial scheduling conference. Within forty-five (45) days after service of the asserted claims and preliminary infringement contentions, the party opposing the claim of patent infringement is required to serve its preliminary non-infringement and invalidity contentions. All of these disclosures require extensive work by the parties, including but not limited to, analysis, preparation of claim charts, production of documents, and translations of any items not in English. The reexamination creates the significant possibility that the USPTO will invalidate or narrow some or all of the claims in the ‘796 patent. If this case is not stayed, the parties will invest hours upon hours of work in patent analysis on what is essentially a moving target. To prevent duplication of effort

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<sup>5</sup> Additionally, this action should be stayed as to the copyright infringement and unfair competition claims because this entire case arises out of the accused VisRx product, which is the product alleged to infringe the ‘796 patent.

and a waste of resources by the parties and the Court, the litigation should be stayed until after the reexamination proceedings are complete.

In short, there is no question that there are enormous efficiencies to be gained from staying this case pending resolution of the reexamination of the patent-in-suit. After the reexamination, it is possible that the case will become moot, that the issues will be streamlined and the Court will have the benefit of the view of the USPTO. Such benefits cannot be denied and clearly support a stay.

### **3. The Stage of This Case Favors a Stay.**

The current stage of this case also supports a stay. In fact, many courts have granted such stays where the case had progressed to a much later stage than the present case. For example, in *Grayling Indus.*, the court granted a stay even though discovery had been completed and trial was imminent. 19 U.S.P.Q.2d at 1874. The *Grayling* court found that the efficiencies that would be provided to the court and the parties as a result of awaiting the outcome of the reexamination outweighed any increased cost of a stay. *Id.* Again in *Loffland Brothers*, the Western District of Oklahoma granted a stay two and a half months before the jury trial was scheduled to begin. 225 U.S.P.Q. 886. In another example, the court in *Emhart Indus.* granted a stay despite the fact that the discovery cut-off had passed because the reexamination would result in simplification of the issues and less complexity at trial. 3 U.S.P.Q.2d at 1891-92.

The instant case is in its infancy. In fact, the Defendants have not even filed an answer or otherwise responded to the Amended Complaint. The early stage of this litigation, combined with the clear efficiencies that will result from staying this case until the reexamination is resolved by the USPTO, unquestionably favors a stay of this case. *See ASCII Corp.*, 844 F.

Supp. at 1381 (granting stay where “the parties are in the initial stages of the lawsuit and have undertaken little or no discovery” and “the case has not been set for trial”).

#### **IV. CONCLUSION**

The outcome of the reexamination of the patent-in-suit by the USPTO will have a substantial effect on the posture of this case. The reexamination deals with the validity of the patent-in-suit as well as other issues, such as proper claim construction and the scope of the claims. All of these issues have a direct bearing on the instant action.

Given the significant reasons to stay this case and the lack of undue prejudice to the Plaintiffs if such a stay is granted, Defendants respectfully request that this Court stay all further proceedings in this case (including answering the Amended Complaint), pending the outcome of the reexamination before the USPTO.

Respectfully submitted this 30<sup>th</sup> day of November, 2007.

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Defendants. )  
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**CERTIFICATE OF SERVICE**

I hereby certify that I have this date filed electronically the within and foregoing **Memorandum in Support of Defendants' Motion to Stay Action Pending Reexamination of U.S. Patent No. 6,270,976** with the Clerk of Court using the CM/ECF system, which will automatically send e-mail notification of such filing to the following attorney of record:

Robert J. Morris

jmorris@smithlaw.com

This 30th day of November, 2007.

/s/ Benjamin F. Sidbury